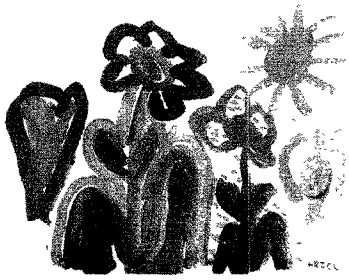

ELIZABETH GLASER PEDIATRIC AIDS FOUNDATION

July 8, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rockville, Maryland 20857

Subject: Comments on Docket Number 2004D-0228, Guidance for Industry Fixed Dose Combinations and Co-Packaged Drug Products for Treatment of HIV/AIDS

Dear Sir/Madam:

The Elizabeth Glaser Pediatric AIDS Foundation welcomes the opportunity to comment on the Food and Drug Administration's (FDA) draft guidance for Industry for Fixed Dose Combination (FDC) and Co-packaged Drug Products for Treatment of HIV/AIDS. We applaud the FDA for publishing this guidance which has the potential to streamline the process of approving essential HIV/AIDS drugs. Speaking from the vantage point of an implementer of care and treatment programs, by facilitating the approval of quality non-brand drugs that can be three to four times cheaper than brand name drugs, this guidance also has the strong potential to strengthen and expand our ability to serve larger numbers of children and adults in developing countries who are in desperate need of HIV/AIDS drugs. We appreciate the opportunity to make comments to help improve the process so that people around the world have access to low-cost, safe and effective HIV/AIDS drugs as quickly as possible.

For over 15 years, the Elizabeth Glaser Pediatric AIDS Foundation has been a leading advocate for children and families. The Foundation's mission creates a future of hope for children and families worldwide by eradicating pediatric AIDS, providing care and treatment for people with HIV/AIDS, and accelerating the discovery of new treatments for other serious and life-threatening pediatric illnesses. In February 2004, the Foundation was awarded a grant in partnership with the Centers for Disease Control and Prevention to provide care and treatment to children and adults in the following 4 countries in sub-Saharan Africa: Cote d'Ivoire, South Africa, Tanzania, and Zambia. As of mid-June, programs funded by the Foundation have already enrolled 600 people on treatment and aims to have 7,000 to 10,000 on treatment in the first year of implementation. A priority of the Foundation's programs is to treat children and ensure that they have the same access to appropriate medications and services as adults.

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Pediatric Testing

The lack of pediatric testing of drugs was one of the main reasons for the creation of the Foundation. Ariel Glaser, Elizabeth Glaser's daughter, lost her life in 1988 in part because at the time, HIV/AIDS drugs had not been tested and were not available for use by children. Since then, the Foundation has fought successfully for proper incentives and legal protections to ensure that children are not forgotten when it comes to ensuring the safety and efficacy of the drugs they use.

However, we are now at risk of repeating the same mistake abroad in regard to the lack of proper pediatric drug testing and appropriate pediatric formulations. Each day, 2,000 children around the world die of HIV/AIDS, and approximately 700,000 children are infected with the virus every year. Without treatment, the majority of children born with HIV in the developing world will die by age five. The chances of long-term survival and a productive adulthood improve dramatically with sustained drug treatment initiated in infants and children. In the developed world, we have shown that treating children can be effective and safe, but only if the drugs are administered correctly. As we move to provide urgently needed care and treatment to those infected with HIV/AIDS in developing nations, we must take all steps necessary to guarantee that children have access to drugs that are appropriately dosed and formulated for their use.

HIV affects children differently than it does adults. Therefore, it is essential that children have access to drugs that are appropriate and suitable for their use. The fact that most brand name drugs are formulated for all pediatric age groups and many have appropriate dosing information for certain age groups is a notable accomplishment. However, we are still missing crucial dosing information for the youngest children. There is an even more serious problem with non-brand drugs because few are tested or formulated for use in children of any age group. Imprecise dosing guidelines jeopardize children's lives. Too much medication can be toxic, and too little will not effectively suppress the virus. Over time, under-dosing can lead to drug resistance, a particularly serious concern for children since they need effective medications to manage their disease for life.

We are pleased that the guidance specifically references the Pediatric Research Equity Act of 2003 (PREA). The Foundation led the fight to pass PREA to give the FDA the authority to require manufacturers to test the safety and dosing of all new medicines and some already marketed medicines as well as to develop appropriate formulations for children. However, if we are to ensure that children have the same access to lifesaving AIDS drugs as adults, it will be necessary for the FDA to use its full authority under PREA to insist that needed pediatric studies be conducted without delay.

We understand that there are instances when pediatric studies cannot be done at the same time as adult studies and PREA provides the FDA flexibility to defer or waive pediatric studies. Waivers may be granted for reasons of feasibility or safety, while deferrals may be granted for medical or ethical reasons. However, in determining whether to grant a waiver or deferral, it is essential that FDA strongly consider the needs of children and the medical and ethical implication of children not having access to safe and effective AIDS drugs. In addition, when deferrals are granted, it is critical that the FDA insist that the studies be completed within an appropriate timeframe.

It will be important that decisions related to the granting of waivers or deferrals of pediatric studies for drugs approved under the expedited system be completely transparent so that the public has confidence in the process and, in the case of deferrals, so that providers have a clear sense of when needed pediatric dosing information and formulations will be available for their patients. Specifically, we urge you to amend the guidance to include a process for indicating on the FDA's Web site a listing of which drugs have received waivers or deferrals, and the reason for the waiver or deferral. In the case of drugs for which a deferral of pediatric studies has been granted, the Web site should also include the types of studies that are being or will be conducted, the pediatric subpopulations being studied, whether pediatric formulations are being developed and the timeline for completion of the studies.

Adverse Event Reporting

It is also important that the FDA provides detailed information in the final guidance about how adverse events will be reported, monitored and acted upon for brand and non-brand medicines approved under the expedited process. As potential purchasers and providers of these medications, it is critical that we understand the FDA's adverse event process under this expedited system and how, if at all, we will be asked to participate in this process. In developing this process, we urge the FDA to ensure that it is simple and does not hinder the rapid expansion of drugs to treat HIV/AIDS in developing nations.

Encouraging Industry Participation

While we commend the Administration for working quickly to create an expedited process for HIV/AIDS drugs, this process will be of little use if companies do not submit applications. While we understand that it is each company's responsibility to apply, the Foundation is urging companies to work with the FDA on this process. With that same sense of partnership, the Administration and the FDA must also do everything they can to encourage and assist companies to submit high quality applications that can be approved in a swift manner.

We appreciate the opportunity to comment on this guidance and hope the FDA will continue to prioritize the needs of children both here in the United States and around the world. If you have any questions, or if we can be helpful to you in any way, please contact me or Natasha Bilimoria, Senior Public Policy Officer at 202-296-9165.

Sincerely,

Kate Carr

Kate Carr
President and CEO